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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,049	09/25/2000	Freda D. Miller	CIBT-P03-120	4083

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BOSTON, MA 02110-2624

EXAMINER
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MURPHY, JOSEPH F

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 05/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/670,049

Applicant(s)

MILLER ET AL.

Examiner

Joseph F Murphy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 and 21-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 7. 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Formal Matters***

New claims 35-42 were added in Paper No. 9, 3/15/2002.

Applicant's election with traverse of Group II, claims 18-20 in Paper No. 9, 3/15/2002 is acknowledged. The traversal is on the ground(s) that the claims encompass overlapping subject matter. This is not found persuasive for the following reasons. Applicant's attention is directed to MPEP 808.02 which states that "Where the related inventions as claimed are shown to be distinct under the criteria of MPEP 806.05 (c-i), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: (A) Separate classification thereof; (B) A separate status in the art when they are classifiable together; (C) A different field of search." As set forth in the Restriction requirement, Group I is classified in class 435, subclass 325; Group II is classified in class 435, subclass 377; Group III is classified in class 800, subclass 8. New claims 35-42 are classified in class 435, subclass 383.

The separate classification established for each Group demonstrates that each distinct Group has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Thus, the Restriction requirement is proper.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-17, 21-42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b). Claims 18-20 are under consideration.

***Claim Rejections - 35 USC § 112 second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "substantially" in claims 18-19 is a relative term which renders the claims indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention. Claim 20 is rejected insofar as they depend on the recitation of the term "substantially".

***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 18-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Sosnowski et al. (1995).

Sosnowski et al.(page 38, column 1, second paragraph to column 2, first paragraph) teaches a method of establishment in primary culture of olfactory epithelium isolated from adult mouse. Based upon immunoreactivity (page 45, column 1, fourth paragraph) to antibodies specific for intermediate filament proteins, the cells present in cultures were identified as neurons, glia or epithelial cells. Thus, the disclosure of Sosnowski meets the limitations of claims 18-20 of a method of producing a population of at least ten cells through the isolation of

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progenitor cells from peripheral tissue, in this instance olfactory epithelium, of a postnatal mammal. The cells isolated by Sosnowski et al. have been shown to be multipotent, due to the presence in culture of several cell types, thus meeting the limitation of claims 18-20.

Claims 18-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ronnette et al. (U.S. Patent No. 5,318,907).

Ronnette et al. (column 6 line 58 to column 7 line 46) discloses the isolation of cells from the olfactory epithelium of neonatal rats, and their establishment in primary culture. The presence of both neurons and glial cells is demonstrated through immunoreactivity with antibodies specific for neurons (anti-neuron-specific enolase) and glial cells (anti-glial fibrillary acidic protein) (column 8, lines 34-47). The disclosure of Ronnette et al. meets the limitations of claims 18-20 through the disclosure of a method of isolation of precursor cells from isolated olfactory epithelium. The development in culture of neuronal cells indicates the presence of neural stem cells and neural progenitor cells, thus meeting the limitations of claims 18-20. The presence in culture of glial cells, together with the presence of neurons demonstrates that the cells are multipotent, thus meeting the limitations of claims 18-20. Ronnette et al. discloses a kit, comprising an isolated neuron, thus meeting the limitation of claim 48 for a kit comprising a mitotic or differentiated cell that is the progeny of a precursor cell derived from peripheral tissue comprising a sensory receptor.

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***Conclusion***

No claim is allowed.

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph F. Murphy whose telephone number is 703-305-7245.


The examiner can normally be reached on M-F 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 703-308-6564. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Joseph F. Murphy, Ph. D.  
Patent Examiner  
Art Unit 1646  
April 30, 2002



DAVID S. ROMEO  
PRIMARY EXAMINER